SYNTHES®

K102722

JAN 27 2011

2. 510(k) Summary

Sponsor:	Synthes Biomaterials 1230 Wilson Drive West Chester, PA 19380
Company Contact	Jeffrey L. Dow, JD Director, Clinical & Regulatory Affairs Synthes Biomaterials 484 356 9720 dow.jeff@synthes.com
Device Name:	Norian Drillable™ Inject and Norian Drillable™ Fast Set Putty™
Classification:	Class II, 21 CFR §888.3045 Filler, bone void, calcium compounds.
Product Codes	MQV, OIS
Predicate Devices	Norian SRS Bone Void Filler and Norian SRS Fast Set Putty (K073303)
Device Description:	Norian Drillable Inject and Norian Drillable Fast Set Putty are moldable, biocompatible bone void fillers with added reinforcing fibers. Norian Drillable Inject and Norian Drillable Fast Set Putty are intended to be placed into bony voids or defects of the extremities or pelvis either before or after final fixation. The material can be drilled and tapped, and screws can be placed through it at any time during or after the setting process. When fully cured, the composition formed closely approximates the mineral phase of bone. The product is available in two delivery forms. Norian Drillable Inject is an injectable paste that is mixed with an automatic mixer, and Norian Drillable Fast Set Putty is manually mixed with a cup and spatula. Norian Drillable Inject is provided in a sterile pouch (the "Rotary Pouch"). The Rotary Pouch is constructed of a clear-film outer pouch and a foil laminate inner pouch with an attached delivery syringe. The Rotary Pouch contains sterile powder with fibers and is designed with an injection port for the purpose of adding the mixing solution to the pouch. The mixing solution is contained in the Solution Syringe, which is

packaged separately.

The Rotary Pouch is designed to be placed in a reusable mixer (the "Rotary Mixer") where the two components are mixed together to form a smooth, viscous paste. The paste remains injectable for approximately 5 minutes at 18°-23°C / 64°-73°F. At body temperature (37°C / 98.6°F), Norian Drillable Inject begins to harden after 2 minutes and sets in approximately 10 minutes. Norian Drillable Inject is slowly resorbed over a period of years and replaced with bone during the healing process.

Norian Drillable Fast Set Putty is supplied in two containers. The mixing cup holds sterile powder with fibers and the Solution Syringe holds sterile solution. When the powder and solution are mixed together with the provided cup and spatula, the resultant putty material can be manipulated for two minutes at 18°-23°C / 64°-73°F.

At body temperature (37°C / 98.6°F), Norian Drillable Fast Set Putty begins to harden after 2 minutes and sets in approximately 3 to 6 minutes. Norian Drillable Fast Set Putty is slowly resorbed over a period of years and replaced with bone during the healing process.

Intended Use: Norian Drillable Inject and Norian Drillable Fast Set Putty are intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. Norian Drillable Inject and Norian Drillable Fast Set Putty can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject and Norian Drillable Fast Set Putty are intended to be placed into bony voids either before or after final fixation.

Substantial Equivalence: Documentation is provided that demonstrates that Norian Drillable is substantially equivalent[4] to other legally marketed devices.

[4] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1230 Wilson Drive
West Chester, PA 19380

JAN 27 2011

Re: K102722
Device Name: Norian Drillable Inject and Norian Drillable Fast Set Putty
Regulation Number: 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: January 14, 2011
Received: January 18, 2011

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

K102722

1. Indications for Use Statement

Norian Drillable Inject and Norian Drillable *Fast Set Putty* are intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. Norian Drillable Inject and Norian Drillable *Fast Set Putty* can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject and Norian Drillable *Fast Set Putty* are intended to be placed into bony voids either before or after final fixation.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102722